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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Insys Manufacturing, LLC

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been delegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on October 4, 2018, Insys Manufacturing, LLC, 811 Paloma Drive, Suite C, Round Rock, Texas 78665, applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled Substance	Drug Code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to manufacture bulk synthetic active pharmaceutical ingredients (APIs) for product development and distribution to its customers. No other activity for these drug codes are authorized for this registration.

Dated: November 16, 2018.

John J. Martin,

Assistant Administrator.

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